knowledge. *Pennock* v. *Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829). Petitioners agree that knowledge already in the public domain should "remain there for the free use of the public." *Aronson* v. *Quick Point Pencil Co*., 440 U.S. 257, 262 (1979). Knowledge exists in the public domain, however, only when it is publicly accessible. There is no coherent sense in which a patent provides a publicly accessible description of an invention that has not been recognized.

In any event, there are legal rules that protect those truly and innocently engaged in the practice of prior art. Where an accused infringer legitimately practices a prior art process that necessarily infringes, the infringement would be addressed in determining whether there are appropriate legal or equitable remedies under the facts of the case. See *Embrex, Inc.*, 216 F.3d at 1353 (Rader, J., concurring) ("the amount, quantum, or economic effect of wrongful conduct is central to the damages assessment"). Moreover, in other jurisdictions, the legitimate practice of prior art has been protected by making that fact a common law defense to a claim of infringement. See, *e.g.*, *Gillette Safety Razor Co.* v. *Anglo Am. Trading Co.*, (1913) 30 R.P.C. 465. Clearly, if it chose to do so, in the context of this case, this Court could address whether and the extent to which a practice of the prior art should be legally protected. But, the Federal Circuit may not eliminate the recognition requirement, and end this Court's rule that accidental prior use does not inherently anticipate, based on concerns about whether such a doctrine would sometimes remove prior art from the public domain. It is for this Court to balance the interests implicated by its own precedent.

Finally, the patent at issue does not preclude practice of the prior art. Apotex argued in the district court that it developed its own process to make anhydrate. Moreover, Apotex brought hemihydrate into its facilities, thereby seeding them, and uses an aqueous coating for its tablets, App. 128a-130a, actions which promote the formation of hemihydrate. In fact, in this case, the Federal Circuit is essentially saying not only

that the prior art inherently anticipated a product it did not describe and that was not recognized, but also that the prior art anticipated a product that it did not initially produce. Neither the elimination of the recognition requirement nor the retroactive re-definition of the prior art can be reconciled with this Court's definition of inherent anticipation.

D. The United States claims that the Federal Circuit's rule will not threaten the massive investment required to discover and invent new products because the discovery or invention of previously undetected products in the prior art can receive patent protection through proper claiming. US Br. 14 (quoting App. 23a). First, this argument ignores the devastating effect of the holding on existing patents. As Judge Newman explained, "[t]he patentability of antibiotics, hormones, antibodies, and myriad other previously unknown or unisolated products would be called into question by this new ruling, giving rise to uncertainty as to existing patents, as well as negation of searches for the beneficial compounds of existing materials." App. 59a.

Second, the threats to investigation and innovation cannot be brushed aside by the invocation of "proper claiming." Inventors and innovators do not have some prophetic ability, or precognition that would enable them to craft a claim for a product that will protect it from some future discovery that a prior art patent results in the production, albeit undetected, of the same product. At a minimum, the new rule requires a significant modification in current patent practice, in which patentees generally claim new compounds without qualification to protect their discovery. All these patents are now subject to an invalidity attack if an infringer can make a post hoc showing that a valuable patented compound was produced as an unknown, undetectable impurity or metabolite in a previously disclosed compound or process.

Prominent authorities do *not* view proper claiming as an antidote to the damage caused by the new Federal Circuit rule. As the dissent in *Schering Corp. v. Geneva Pharma-*

ceuticals, Inc., 348 F.3d 992 (Fed. Cir. 2003) stated, the unprecedented expansion of the inherent anticipation doctrine "effectively preclud[es] virtually all patents on [compounds that turn out to be] human metabolites of drugs." *Id.* at 995. Claims to heretofore undiscovered natural products are now per se anticipated. Professors Chisum and Smith have stated:

> [I]t is not clear that a broad inherent anticipation rule is good. . . . [A] patent on a new compound with pharmaceutical activity could be invalid if the compound was later shown to be a metabolite of some other drug, even if the other drug was used for a seemingly unrelated purpose. [D. Chisum & M. Smith, *SmithKline: How the Expanding Inherent Anticipation Doctrine Affects Chemical Patents, IP Newsletter* (Morrison/Foerster, S.F. Cla.), June 2005, at 5 *available at* http://www.mofo.com/docs/PDF/IPNewsletter0605.pdf.]

No claim drafting techniques can prevent the uncertainty resulting from the Federal Circuit's new rule and the damage that such uncertainty will cause to innovation and discovery.

Finally, the United States ignores the clear language of 35 U.S.C. § 101 which provides that "[w]hoever invents or discovers any new . . . composition of matter . . . may obtain a patent therefor." *Id.* Petitioner invented a new composition of matter – the hemihydrate – not known to exist in the prior art, and was thus expressly entitled to claim it under § 101.

CONCLUSION

For the foregoing reasons and those set forth in the Petition and Reply, the petition for certiorari should be granted.

Respectfully submitted,

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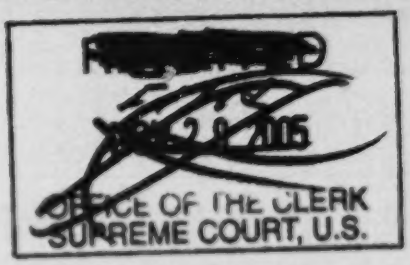

No. 05-489

IN THE

Supreme Court of the United States

SMITHKLINE BEECHAM CORPORATION, SMITHKLINE BEECHAM P.L.C., GLAXOSMITHKLINE, P.L.C., AND BEECHAM GROUP, PLC,

Petitioners,

v.

APOTEX CORPORATION, APOTEX, INC. AND TORPHARM, INC.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

REPLY BRIEF

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INTRODUCTION AND SUMMARY OF ARGUMENT

The petition demonstrates that the rule of law adopted in *Schering Corp.* v. *Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373 (Fed. Cir.), *reh'g and reh'g en banc denied*, 348 F.3d 992 (Fed. Cir. 2003), and expanded in the decision below, conflicts with *Tilghman* v. *Proctor*, 102 U.S. 707 (1881), *Eibel Process Co.* v. *Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923), and other decisions. The consequences for patent law and its purposes are profound and harmful. In response, Apotex melodramatically claims that SmithKline Beecham proposes to violate fundamental tenets of patent law and offers three sets of arguments in opposing certiorari. But, in fact, petitioner *embraces* the principles of patent law recited by Apotex; and, as we now show, it is Apotex which seeks to do violence to the established law of inherent anticipation.

First, Apotex claims that there is no conflict in authority. To illustrate this point, Apotex asserts that it has the unanimous support of the Federal Circuit – a claim that is easily disproved. Apotex also cites clearly inapposite cases and unsuccessfully attempts to distinguish *Tilghman*, *Eibel*, and other decisions holding that an unappreciated invention or discovery is *not* inherently anticipated by the prior art. In fact, the Federal Circuit's expansive new doctrine of inherent anticipation contravenes this Court's precedent, and for that reason alone warrants review.

Second, Apotex wrongly claims that SmithKline Beecham advocates a rule of inherent anticipation that would deprive the public of its right to practice the prior art of an expired patent. Petitioner fully agrees that a patent cannot prohibit practice of the prior art or remove something from the public domain. However, the hemihydrate, unknown and undetected, was never within the public domain, and thus Apotex cannot be properly said to be practicing the

procedures of the Ferrosan patent. Accordingly, petitioner's position is wholly consistent with the practice of prior art in the public domain.

Finally, Apotex contends that the rule of law at issue is not important to patent law and its underlying public policies. This claim ignores the threat to innovation that judges and numerous others conclude is presented by the radical expansion of the doctrine of inherent anticipation that now governs in the Federal Circuit. See Briefs of Pharmaceutical Research and Manufacturers of America and Washington Legal Foundation, filed Nov. 16, 2005; B. Eretschneider, *Making Us Crazy: The US Court of Appeals Messes with Inherent Anticipation*, Patent World, Nov. 2005, at 17-19.

ARGUMENT

I. THE FEDERAL CIRCUIT'S RULE CONFLICTS WITH THIS COURT'S DECISIONS AND ESTABLISHED PATENT LAW.

Apotex asserts that under established law, a patent claim is inherently anticipated whenever the claimed subject matter becomes the inevitable product of the prior art, even if that subject matter was wholly unappreciated in the prior art. This Court's decisions say the opposite; accordingly, Apotex's claims are meritless.

Initially, Apotex contends that there is no disagreement among Federal Circuit judges on this issue by claiming that no judge dissented from the denial of rehearing *en banc* below. Opp. 7, 15. That assertion is badly misleading. Clearly, Judge Newman, who dissented from the *initial* denial of rehearing *en banc*, strongly disagrees with the Federal Circuit's holding. App. 57a-59a. She also concluded that the decision conflicts with *Tilghman* and *Eibel*. *Id.* Moreover, in *Schering*, Judges Newman, Lourie and Gajarsa voted to rehear *en banc* the decision that jettisoned half of the established test for inherent anticipation. 348 F.3d at 994.

Second, Apotex claims that authority from both this Court and the Federal Circuit supports its position, but the cited cases do not find inherent anticipation based on the prior unappreciated invention of a novel product. Instead, these cases stand only for the unexceptional proposition that unappreciated *characteristics* of products and processes described in the prior art are inherently anticipated. The lone case cited from this Court, *Foley* v. *United States*, 260 U.S. 667 (1923), involved precisely this situation. The product created by the process at issue was known, and the allegedly novel invention simply identified a new characteristic of the product. In contrast, petitioner does not assert that a prior product has a newly-discovered characteristic, but instead claims a wholly new product unappreciated by the prior art.

Similarly, in *Atlas Powder Co.* v. *IRECO Inc.*, 190 F.3d 1342 (Fed. Cir. 1999), the Federal Circuit did not find inherent anticipation in an unappreciated creation of the prior art. Instead, the prior art disclosed a blasting compound but did not recognize the existence of interstitial air (*i.e.*, sufficient aeration). The court found that the requirement of interstitial air was inherently anticipated by the prior art because the prior art compositions contained sufficient air. *Id.* at 1345. As the court explained,

> [a]rtisans of ordinary skill may not recognize the *inherent characteristics or functioning of the prior art.* However, the discovery of a previously unappreciated *property* of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. [*Id.* at 1347 (emphasis supplied; internal citations omitted).][1]

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[1] The court specifically analogized *Atlas Powder* to *Titanium Metals Corp.* v. *Banner*, 778 F.2d 775, 777 (Fed. Cir. 1985), where a prior art reference disclosed a metal alloy, but not its corrosive-resistant properties.

Like *Foley* and *Atlas Powder*, the court in *Eli Lilly & Co.* v. *Barr Laboratories, Inc.*, 251 F.3d 955, 970 (Fed. Cir. 2001), found that a claim is inherently anticipated by a prior art patent because the later claim disclosed only a characteristic of the prior art product (not a novel product).[2] These cases show that scientific advances revealing the inherent characteristics of a product or process described in the prior art do not result in patentable claims. None finds inherent anticipation of an unappreciated, separate *product* in prior art.

Third, Apotex parrots the Federal Circuit's attempted distinction of *Tilghman* and *Eibel*, arguing that in both cases the prior art may have produced the claimed invention only *accidentally*, and that in neither case was it certain that the prior art produced the subject matter of the later claim. Opp. 11-12. As the petition explained (12-17), this crabbed reading of that precedent is inconsistent with its language and its application by other federal courts. In both *Tilghman* and *Eibel*, this Court expressly assumed that the prior art inevitably produced the newly-claimed invention, and nonetheless held that the new invention was *not anticipated because it had not previously been appreciated.* In *Carnegie Steel Co.* v. *Cambria Iron Co.*, 185 U.S. 403 (1902), too, the Court declined to find inherent anticipation, relying in part on the fact that the subject matter of the claim had not been appreciated. This Court's cases thus demonstrate that even where a claimed invention is necessarily disclosed in the prior art, it is not inherently anticipated unless a person skilled in the art appreciated that fact.

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[2] *W.L. Gore & Assocs.* v. *Garlock*, 721 F.2d 1540 (Fed. Cir. 1983), and *Ecolochem, Inc.* v. *Southern Cal. Edison Co.*, 863 F. Supp. 1165 (C.D. Cal. 1994), *aff'd in part, rev'd in part by* 91 F.3d 169 (Fed. Cir. 1996), are distinguishable for the same reason. *See Gore*, 721 F.2d at 1548 (the "consistent reproducible use of" a patented process was inherently anticipated by prior art describing the same process even if the operators of the machine failed to appreciate aspects of that process); *Ecolochem*, 863 F. Supp. at 1179 n.17 (cation exchange resins have the characteristic quality of removing cation contaminants).

Next, Apotex makes a wholly unpersuasive attempt to distinguish numerous lower court decisions that read *Tilghman* and *Eibel* as SmithKline Beecham does. Two of these cases involved the production of unrecognized trace amounts of tetracycline while practicing the prior art to produce aureomycin. Apotex irrelevantly says that these cases raised the question whether Pfizer's patent on tetracycline should be cancelled because Pfizer had failed to inform the Patent Office that trace amounts of tetracycline were produced in the manufacture of aureomycin. Opp. 14. In both cases, the court found that Pfizer's omission did not constitute fraud and that the prior art did not inherently anticipate tetracycline *because the co-production of that substance had been undetected and unappreciated.* See *In re Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions*, 498 F. Supp. 28 (E.D. Pa. 1980) ("[c]oproduction of small amounts of tetracycline in the prior art which was unrecognized at the time . . . could not act as a bar to a patent on tetracycline"), *aff'd* 676 F.2d 51 (3d Cir. 1982); *North Carolina* v. *Chas. Pfizer & Co.*, 384 F. Supp. 265, 278 n.17 (E.D.N.C. 1974) (same), *aff'd*, 537 F.2d 67 (4th Cir. 1976).

Apotex's attempt to distinguish *Ritter* v. *Rohm & Haas Co.*, 271 F. Supp. 313 (S.D.N.Y. 1967), fares no better. Apotex contends that *Ritter* stands only for the proposition that the prior art results must be inevitable to anticipate a patent claim, and does not support the assertion that an unappreciated product in the prior art is not anticipated by that prior art. But, *Ritter* holds that the prior use of a process that produced esters did not preclude a patent on the same process to produce amides, an unappreciated product. The court's analysis focused *not* on inevitability, but instead on lack of appreciation:

> A previously unrecognized process . . . is not anticipated merely because a separate, known process . . . leading to a totally different result (an ester), happens to have the same reaction conditions and initial ingredients.

> Similarly, where products are "unwittingly produced, whilst the operators were in pursuit of other and different results, without exciting attention and without its even being known what was done or how it had been done, it would be absurd" to hold that this is anticipation." [*Id.* at 345-46.]

Least persuasive is the attempted distinction of *In re Seaborg*, 328 F.2d 996 (C.C.P.A. 1964). Apotex asserts that the court found that the prior art did not anticipate the discovery of an isotope that was the unappreciated co-product of that prior art based on the court's "considerable doubt as to whether operation of the reactor in fact produced the claimed isotope." Opp. 14. To the contrary, the opinion makes clear that the prior process inevitably produced trace amounts of the new isotope and that inherent anticipation was *denied* because that isotope had been the unappreciated co-product of the prior art. See 328 F.2d at 999.[3]

Finally, Apotex asserts that *Schering* resolved the conflict among prior cases about whether appreciation is required for inherent anticipation. Petitioner agrees that *Schering*, as applied and expanded below, states the controlling rule of law in the Federal Circuit, the only circuit with appellate jurisdiction over patent questions. The problem, however, is that the Federal Circuit's rule is wrong and conflicts with the doctrine of inherent anticipation articulated in this Court's decisions and established law.[4]

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[3] Apotex acknowledges that *Rosco, Inc.* v. *Mirror Lite Co.*, 304 F.3d 1373 (Fed. Cir. 2002), and *Silvestri* v. *Grant*, 496 F.2d 593 (C.C.P.A. 1974), hold that prior art does not anticipate where the inventor does not appreciate the newly-claimed subject matter, Opp. 15, but asserts that these cases are distinguishable because they involve prior inventions whose rules of inherent anticipation allegedly differ from those applicable to prior discoveries. Apotex cites no support for this claimed distinction. In fact, there is a single rule – prior art does not anticipate a subsequent claim for an unappreciated product of that prior art.

[4] Twice Apotex seeks to dissuade the Court from granting review by suggesting that the existence of the hemihydrate was both known and

II. THE RULE OF LAW PETITIONER ADVOCATES WOULD NOT PREVENT THE PRACTICE OF THE PRIOR ART IN AN EXPIRED PATENT.

Apotex expends significant energy describing a tenet of patent law holding that the public is entitled to practice the subject matter of prior art once the patent on that prior art expires, and arguing that SmithKline Beecham's position would deprive the public of that right. Opp. 5-7. SmithKline Beecham, however, wholeheartedly endorses this basic proposition: A patent cannot prohibit practice of the prior art or remove subject matter from the public domain. But, the hemihydrate, undetected and unappreciated, was not within the public domain, and Apotex thus cannot properly be said to be practicing the prior art described in the 1977 Ferrosan patent. Accordingly, Apotex's contention that SmithKline Beecham is seeking to block the practice of prior art in the public domain is clearly wrong.

More specifically, Apotex does not propose to practice the claims of the prior art patent producing a paroxetine product as described by the 1977 Ferrosan patent. Instead, Apotex proposes to produce that product with hemihydrate. Indeed, in 1988, SmithKline Beecham's scientists published that seeds of hemihydrate and water are factors that cause conversion of the anhydrate to the hemihydrate. P.C. Buxton et al., *Solid-State Forms of Paroxetine Hydrochloride*, 42

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knowable at the time of the Ferrosan patent. Opp. 1, 13 (citing testimony that polymorphism was a "known phenomenon") This is contrary to both lower courts' factual findings. *See* App. 9a, 15a, 17a, 125a-126a, 131a ("the hemihydrate polymorph of paroxetine was unknown either when the patent application was filed or in 1977 when the patent was granted. Nor has Apotex shown that hemihydrate, the invention claimed by patent 723, was obvious given the prior art"). Indeed, the district court did not find clear and convincing evidence that the hemihydrate *existed* in the prior art, *id.* at. 132a; and expert testimony in the trial court confirmed that the existence of the hemihydrate could not have been predicted. *See* Trial Tr. 138-39. In any event, SmithKline Beecham does not seek to patent polymorphism, but instead the undetected, unappreciated hemihydrate.